



ARA-US-P1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Li et al. Group Art Unit:

Serial No.: 10/618,133 Examiner:

Filed: July 11, 2003

Title: APPARATUS AND METHOD FOR CONTINUOUS
DEPYROGENATION AND PRODUCTION OF
STERILE WATER FOR INJECTION

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 CFR § 1.56, Applicants request that the references cited in the accompanying Form PTO/SB/08A (10-96) be considered by the examiner in the above-entitled application and made of record therein. Copies of the cited references are enclosed.

Respectfully submitted,


Joshua S. Broitman
Registration No. 38,006

October 10, 2003

Date

OSTRAGER CHONG & FLAHERTY LLP
825 Third Avenue
New York, NY 10022-7519
(212) 826-6565

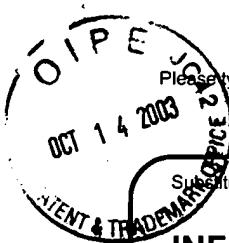
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October 10, 2003
Date


Roberto L. Gomez



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PTO/SB/08A (10-96)

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Shee

of 5

Sheet 1 of 5

Complete if Known

Application Number	10/618,133
Filing Date	07/11/2003
First Named Inventor	Lixiong Li
Group Art Unit	
Examiner Name	
Attorney Docket Number	ARA-US-P1

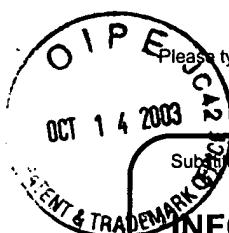
U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
A	6,585,890	B2		Li et al.	07/01/2003	Entire Patent
B	6,485,649	B1		Terava et al.	11/26/2002	Entire Patent
C	6,406,273	B2		Wong	06/18/2002	Entire Patent
D	6,247,903	B1		Wong	06/19/2001	Entire Patent
E	6,167,951	B1		Couch et al.	01/02/2001	Entire Patent
F	6,094,523			Zelina et al.	07/25/2000	Entire Patent
G	6,086,822			Trinidad	07/11/2000	Entire Patent
H	6,030,436			Barclay	02/29/2000	Entire Patent
I	5,949,958			Naperkowski et al.	09/07/1999	Entire Patent
J	5,928,481			Briggs	07/27/1999	Entire Patent
K	5,917,022			Davies	06/29/1999	Entire Patent
L	5,880,438			Parrini et al.	03/09/1999	Entire Patent
M	5,851,293			Lane et al.	12/22/1998	Entire Patent
N	5,717,303			Engel	02/10/1998	Entire Patent
O	5,498,409			Hirayama et al.	03/12/1996	Entire Patent
P	5,401,499			Hirayama et al.	03/28/1995	Entire Patent
Q	5,401,421			Blum	03/28/1995	Entire Patent
R	5,279,821			Hirayama et al.	01/18/1994	Entire Patent
S	5,242,595			Morgart et al.	09/07/1993	Entire Patent
T	5,202,246			Kruse et al.	04/13/1993	Entire Patent

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO		<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/618,133
		Filing Date	07/11/2003
		First Named Inventor	Lixiong Li
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	ARA-US-P1
Sheet	2	of	5

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	U	5,186,020		Rockefeller et al.	02/16/1993	Entire Patent
	V	5,166,123		Agui et al.	11/24/1992	Entire Patent
	w	5,104,546		Filson et al.	04/14/1992	Entire Patent
	X	5,032,265		Jha et al.	07/16/1991	Entire Patent
	Y	5,026,258		Mosley	06/25/1991	Entire Patent
	Z	5,021,391		Agui et al.	06/04/1991	Entire Patent
	AA	4,958,658		Zajac	09/25/1990	Entire Patent
	BB	4,935,150		Iida et al.	06/19/1990	Entire Patent
	CC	4,913,827		Nebel	04/03/1990	Entire Patent
	DD	4,909,942		Sato et al.	03/20/1990	Entire Patent
	EE	4,833,888		Kerner et al.	05/30/1989	Entire Patent
	FF	4,883,596		Agui et al.	11/28/1989	Entire Patent
	GG	4,858,643		Vavra et al.	08/22/1989	Entire Patent
	HH	4,810,388		Trasen	03/07/1989	Entire Patent
	II	4,772,390		Kawai et al.	09/20/1988	Entire Patent
	JJ	4,759,909		Joslyn	07/26/1988	Entire Patent
	KK	4,752,389		Burrows	06/21/1988	Entire Patent
	LL	4,673,733		Chandra et al.	06/16/1987	Entire Patent
	MM	4,648,978		Makinen et al.	03/10/1987	Entire Patent
	NN	4,610,790		Reti et al.	09/09/1986	Entire Patent

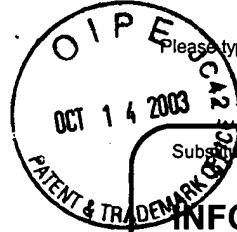
FOREIGN PATENT DOCUMENTS

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 5

Complete if Known	
Application Number	10/618133
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First Named Inventor	Lixiong Li
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Examiner Name	
Attorney Docket Number	ARA-US-P1

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		Number	Kind Code ² (if known)			
OO	4,548,716			Boeve	10/22/1985	Entire Patent
PP	4,547,289			Okano et al.	10/15/1985	Entire Patent
QQ	4,495,067			Klein et al.	01/22/1985	Entire Patent
RR	4,381,239			Chibata et al.	04/26/1983	Entire Patent
SS	4,276,177			Smith	06/30/1981	Entire Patent
TT	4,261,834			deWinter	04/14/1981	Entire Patent
UU	4,182,354			Bergstedt	01/08/1980	Entire Patent
VV	4,070,289			Akcasu	01/24/1978	Entire Patent
WW	4,069,153			Gunther	01/17/1978	Entire Patent
XX	3,870,033			Faylor et al.	03/11/1975	Entire Patent
YY	3,860,494			Hickman	01/14/1975	Entire Patent
ZZ	3,648,438			Arbogast	03/14/1972	Entire Patent
AAA	3,601,378			Hurst	08/24/1971	Entire Patent
BBB	3,068,794			Morris et al.	12/18/1962	Entire Patent
CCC	2,362,724			Shea	11/14/1944	Entire Patent
DDD	2001/0050215	A1		Li et al.	12/13/2001	Entire Patent
EEE	2003/0164339	A1		Li et al.	09/04/2003	Entire Patent

FOREIGN PATENT DOCUMENTS

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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
FFF	JP	4-114661	/		Yasushi et al.	04/15/1992	Entire Patent
GGG	JP	1-203046	/		Jun et al.	08/15/1989	Entire Patent
HHH	JP	59-112888	/		Kazuo et al.	06/29/1984	Entire Patent
III	JP	57-171403	/		Atsushi et al.	10/22/1982	Entire Patent
JJJ	WO	91/04086	\		Huo et al.	04/04/1991	Entire Patent

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/618,133
Sheet	4	of	5	Filing Date	07/11/2003
				First Named Inventor	Lixiong Li
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	ARA-US-P1

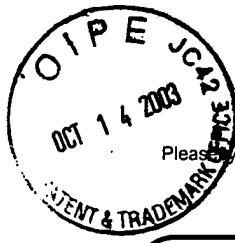
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	KKK	W. DICKINSON BURROWS and JAMES H. NELSON, IV Fluidmakers: Preparation of Sterile Water for Injection in a Field Setting, Journal of Parenteral Science & Technology, May-June 1993, pp. 124-129, Vol. 47 No. 3	/
	LLL	ANDREW W. COLLENTRO, Pharmaceuticals - Practical Microbial Control Techniques for Pharmaceutical Water Purification Systems, Ultrapure Water, March 2002, pp. 53-60	/
	MMM	KIYOSHI TSUJI and SUSAN HARRISON, Dry-Heat Destruction of Lipopolysaccharide: Dry-Heat Destruction Kinetics, Appl. Environ. Microb., Nov. 1978, pp. 710-714, Vol. 36 No. 5	/
	NNN	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Heat Exchangers to Avoid Contamination, Inspection Technical Guide (ITG) No. 34, July 31, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg34.html (last visited March 29, 1999)	/
	OOO	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Pyrogens, Still a Danger, Inspection Technical Guide No. 32, January 12, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg32.html (last visited March 29, 1999)	/
	PPP	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), Guide to Inspections of High Purity Water Systems, pp. 1-9, at www.fda.gov/ora/inspect_ref/igs/high.html (last visited March 24, 1999)	/
	QQQ	KIYOSHI TSUJI and A.R. LEWIS, Dry-Heat Destruction of Lipopolysaccharide: Mathematical Approach to Process Evaluation, Appl. Environ. Microb., Nov. 1978, pp. 715-719, Vol. 36 No. 5	/
	RRR	HANS TRAEGER, Pharmaceuticals - The Presence of Bacteria, Endotoxins, and Biofilms in Pharmaceutical Water, Ultrapure Water, March 2003, pp. 17-22	/
	SSS	ALEX KONOPKA, Pharmaceuticals - Current Issues and System Design Considerations Affecting Pharmaceutical Water Systems, Ultrapure Water, March 2002, pp. 22-30	/
	TTT	DAVID H. PAUL, Back to Basics - The Combining of Reverse Osmosis and Ion Exchange, Ultrapure Water, July/August 2002, pp. 38-40	/
	UUU	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA) ITG Subject: Bacterial Endotoxins/Pyrogens, Inspection Technical Guide (ITG) No. 40, March 20, 1985, pp. 1-10, at www.fda.gov/ora/inspect_ref/itg40.html (last visited March 24, 1999)	/

Examiner Signature	Date Considered
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(use as many sheets as necessary)				Filing Date	07/11/2003
Sheet	5	of	5	First Named Inventor	Lixiong Li
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	ARA-US-P1

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
	VVV	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Water for Pharmaceutical Use, Inspection Technical Guide (ITG) No. 46, December 31, 1986, pp. 1-4, at www.fda.gov/ora/inspect_ref/itg/itg46.html (last visited October 9, 2003)		/
	WWW	EUROPEAN PATENT OFFICE Abstract - Pyrogen Adsorbent and Removal of Pyrogen Using the Same, JP 4-114661, April 15, 1992		/
	XXX	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Resin Carrier, JP 1-203046, August 15, 1989		/
	YYY	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Aqueous Solution, JP 59-112888, June 29, 1984		/
	ZZZ	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen in Water, JP 57- 171403, October 22, 1982		/

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